

## **REMARKS**

### **Status of the Claims**

Claims 1-3 and 5-13 are currently pending in the application. Claims 1-12 stand rejected. Claims 1 and 9 have been amended. Claim 4 has been cancelled. All amendments and cancellations are made without prejudice or disclaimer. New claim 13 has been added. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by the specification at, for instance, page 5, lines 10-11 and lines 16-18 and the amendment to claim 9 is supported at the bottom of page 11. New claim 13 is also supported by the specification at least at page 5, lines 16-18. Reconsideration is respectfully requested.

### **Rejections Under 35 U.S.C. § 102(b)**

Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Chaman et al., *Zhurnal Obshchei Khimii*, 33(10):3342-3349, 1963 (hereinafter, "Chaman I"). Claims 1, 3 and 4 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Chaman et al., *Zhurnal Obshchei Khimii*, 36(9):1608-1613, 1966 (hereinafter, "Chaman II"). Finally, claims 1, 3 and 4 further stand rejected under 35 U.S.C. § 102(b) as being anticipated by Woenckhaus et al., *Zeitschrift fuer Naturforschung*, 20b(4): 400, 1965 (hereinafter, "Woenckhaus et al."). (See, Office Action of January 30, 2008, at page 2, hereinafter, "Office Action"). Claim 4 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection of claim 4. Applicants traverse the rejection as to claims 1 and 3.

The Examiner states that Table compounds XVII, XVI, XVIII of Chaman I anticipate the presently claimed invention when  $R^2$  is H, Cl or OH,  $R^1$  is H, R is  $NH_2$ ,  $m=0$  and  $(Y)_m$  is

methylene. The Examiner also states that compound III of the Chaman II table discloses a compound encompassed by Applicants' claims, where  $R^2$  is dimethylamino,  $R^1$  is H, R is  $NH_2$ ,  $m=0$ ,  $(Y)_m$  is methylene. Finally, the Examiner also cites to Woenckhaus et al., stating that Woenckhaus et al. anticipate the present claims where  $R^1$  is H, R is  $NH_2$ ,  $m=0$  and  $Y_m$  is methylene.

Although Applicants do not agree that the presently claimed compounds and methods of synthesizing said compounds are anticipated by the cited references, to expedite prosecution, the definition for " $(Y)_m$ " in claim 1 has been amended herein without prejudice or disclaimer to recite, in part, "alkylene having 2 to 5 carbon atoms, alkenylene or alkynylene."

Applicants note that in each of the cited references, the compound the Examiner cites has  $Y_m$  defined as "methylene." This subject matter is no longer encompassed by amended claim 1.

Dependent claim 3 is not anticipated as, *inter alia*, depending from a non-anticipated base claim, amended claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1 and 3 are respectfully requested.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at pages 2-3). Claim 4 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection of claim 4. Applicants traverse the rejection as to the remaining claims.

Formula 2, according to the Examiner, requires that the nitrogen atom be double bonded to a carbon, and the carbon bonded to R<sup>6</sup> and R<sup>7</sup>. The Examiner states that this N=C arrangement appears not to be encompassed by the definition of the variable "R" in formula 1 of claim 1. Therefore, the Examiner believes that claim 2 is not narrower in scope as compared to claim 1, at least with respect to the definition of the variable "R."

Although Applicants do not agree that claim 1 is indefinite, to expedite prosecution, claim 1 has been amended to additionally recite, in part, "said R' and R'' are protecting group for amino group, or R' and R'' form benzophenoneimine together with N ..." Support for this amendment may be found at least at page 5, lines 10-11 of the specification.

Thus, at least as amended, claim 1, the definition of R in formula 1 encompasses the N=C arrangement recited in claim 2.

Since no independent reasoning is provided by the Examiner to support the indefiniteness rejection of dependent claims 2, 3 and 5-12, these dependent claims are believed to be definite for, *inter alia*, depending from a definite base claim, amended claim 1.

Reconsideration and withdrawal of the indefiniteness rejection of claims 1-3 and 5-12 are respectfully requested.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-12 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement support in the specification. The Examiner also alleges that the claims lack "an adequate teaching of utility." (*See*, Office Action, at pages 3-24). Claim 4 has been cancelled herein

without prejudice or disclaimer, thus obviating the rejection of claim 4. Applicants traverse the rejection as to the remaining claims.

The Examiner's remarks focus on the unpredictability within the art, including the treatment of a very long laundry list of cancers and viruses at pages 4-24 of the Office Action.

However, the Examiner is respectfully referred to the present specification which explains "how to make" in detail. In addition, "how to use" is described in the specification at least at page 44, line 29 to page 45, line 2, as well as page 1, page 6-15. The Examiner is reminded that, "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." (*See, In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)). Furthermore, Applicants point out that a "patent need not teach, and preferably omits, what is well known in the art." (*See, Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987)).

Furthermore, the claims do not anywhere recite treatment of cancer, treatment of viral infection, or treatment of any type of disease. The presently claimed invention is clearly directed to specific chemical compounds (claims 1-8) and methods of synthesizing said compounds (claims 9-12) which are all explicitly supported in the specification.

The second and third paragraphs of the first page of the present specification disclose that the class of presently claimed compounds may be useful in treatment of cancer and viral infection. This disclosure at page 1 of the specification provides a clear and explicit asserted utility for the presently claimed invention. However, the Examiner seems to believe this asserted utility is insufficient. (*See, Office Action*, at page 3). The Examiner's position is unsupportable

especially in light of the many decades of legal precedent concerning chemical compounds of this family and claims thereto being patentable and in light of the known activity of the class of compounds which encompass the presently claimed compounds. That is, page 1, line 7, of the present specification, discloses the following:

As an anticancer agent or a compound having an antiviral activity, purine compound is conventionally well known, and there are many reports on synthetic intermediates therefor (e.g., WO 00/75158).

Hocek et al., WO 00/75158, referenced above, is entitled, "Novel 6-phenylpurine 9- $\beta$ -D-ribonucleosides with antineoplastic activity, their use for preparing pharmaceutical compositions and pharmaceutical preparations containing such compounds." At page 2 of Hocek et al., it is disclosed that "concerstatics and antileukemic drugs are often pyrimidine or purine derivatives." Particularly, Hocek et al. itself discloses at Examples 2-3, Tables 1-3, pages 8-10, the anticancer activities of exemplary compounds within this class of compounds.

The Examiner has provided no evidence directly contradicting these findings. The Examiner has merely provided conjecture and generalizations which are summarized in a simple conclusory statement that Applicants' specification lacks an adequate teaching of utility. This conclusory statement fails to take into account both the decades of clinical cancer and viral infection research and the decades of legal precedent concerning assertion of a credible, substantial and specific utility.

For instance, the Examiner has provided no evidence or data or information which would lead one of skill in the art to not believe the asserted utility of the presently claimed invention or that directly contradict the findings of such references as Hocek et al. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the

allegation of utility in the specification must be accepted as correct. (*See, In re Kamal et al.*, 398 F.2d 867, 158 USPQ 320 (CCPA 1968), *In re Riat et al.*, 327 F.2d 685, 140 USPQ 471 (CCPA 1964)).

A conclusory statement that the presently claimed invention lacks “an adequate teaching of utility” is clearly insufficient to support an enablement rejection. The Examiner has failed to specify whether the rejection is based on failure to disclose a specific utility, a substantial utility, or a credible utility. It seems that perhaps the Examiner is referring to a lack of credible utility. Applicants have clearly disclosed a specific utility – treatment of cancer or viral infection. Applicants also believe such a utility is substantial, i.e. it is not an assertion of a minimal use, such as use as a paperweight, etc.

If the Examiner is attempting to base the rejection on a lack of credible utility, the Federal Circuit provides the standard for this analysis as follows: “[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result.” (*See, Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992), emphasis added, *see also, E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 U.S.P.Q 1, 10 n.17 (8th Cir. 1980), stating, “A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity.”) Furthermore, “[I]f

an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate." (*See, In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 U.S.P.Q. 396 (CCPA), *reh'g denied*, 480 F.2d 879 (CCPA 1973); *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971)).

Thus, reconsideration and withdrawal of the enablement rejection of claims 1-3 and 5-12 are respectfully requested.


### CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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